

III. Remarks

A. Status of the Application

Claims 12-21 and 31-40 were previously pending. No claims are added or canceled by the present paper. Applicants request reconsideration of the application in light of the following remarks.

B. Drawing Objections

The Office Action objected to the drawings as failing to show every feature of the invention as specified in the claims. However, the Office Action itself also recognized that “[t]he drawings are noted by the Examiner to show the features separately.” Office Action, p. 2. There is simply no requirement that all of the features of the claims be shown together in a single drawing. Rather, as noted by the Office Action, “the **drawings** must show every feature of the invention specified by the claims.” Clearly, and as noted by the Examiner, the drawings of the present application do show every feature recited in the claims. Accordingly, Applicants request the objection to the drawings be withdrawn.

C. Specification Objections

The Office Action objected to the specification as failing to provide proper antecedent basis for the claimed subject matter. In particular, the Office Action asserted that “the recitations that the laterally inserted screws (insertion members) areand not engaging a pedicle of the vertebrae or spaced from the pedicle was not found in the written description.” As noted in MPEP 608.01(o), “an applicant is not limited to the nomenclature used in the application as filed.” Rather, as noted in MPEP § 2173.05(e): “There is no requirement that the words in the claim must match those used in the specification disclosure. Applicants are given a great deal of latitude in how they choose to define their invention so long as the terms and phrases used define the invention with a reasonable degree of clarity and precision.” In that regard, MPEP § 2173.05(a) notes that “The meaning of every term used in a claim should be apparent from the prior art or from the specification and drawings at the time the application is filed. Applicants need not confine themselves to the terminology used in the prior art, but are required to make

clear and precise the terms that are used to define the invention whereby the metes and bounds of the claimed invention can be ascertained.” In the present case, the metes and bounds of the claim language is easily ascertainable and readily apparent from the specification and drawings of the application. The detailed description and the corresponding illustrations in Figs. 3a and 3b, for example, certainly provide the necessary antecedent basis for the claimed subject matter. Accordingly, Applicants request that the objection to the specification be withdrawn.

D. Rejections under 35 U.S.C. §112

Claims 14-16 and 31-40 stand rejected under 35 U.S.C. §112, first paragraph. Specifically, the Office Action notes that “the Examiner fails to see where any of the recited disclosure describe a vertebrae designed to receive such a combination of the two corrective apparatus features inserted in the vertebrae and any particular drawing illustrating a lateral wall that has both corrective apparatus in combination together. What the Examiner has reviewed by the Applicant all describe individual apparatus intended to be used in separate methods of corrective repair, not in combination.” Applicants respectfully disagree.

As noted in Applicants previous response, the “Lateral Correction” portion of the application at paragraphs [0072]-[0119] and Figs. 1-13 explicitly discloses the combination of limitations set forth in claims 14-16 and 31-40. For example, the specification describes the following:

“I. Lateral Correction

In many cases of deformity, such as spondylolisthesis, one or more vertebral bodies can be displaced with respect to other vertebrae or the sacrum. In such a deformity, **it is desirable to reduce the extent of displacement, by re-positioning the displaced bodies from their previous position.**

* * *

In one embodiment, some or all of the natural disc that would have been positioned between the two vertebrae V_L , V_U is typically removed via a discectomy or a similar surgical procedure, the details of which would be known to one of ordinary skill in the art. **Removal of the diseased or degenerated disc results in the**

formation of an intervertebral space S between the upper and lower vertebrae V_U , V_L .

In the present embodiment, **it is desired to insert a prosthetic joint into the intervertebral space S**, similar to the prosthetic joint disclosed in U.S. Ser. No. 10/042,589 filed Jan. 9, 2002, which is incorporated by reference. However, certain changes are required of the above-referenced prosthetic joint.

* * *

Spondylolisthesis has not heretofore been corrected from the lateral surgical approach. However, in some instances, correction of spondylolisthesis may be desirable from a lateral approach due to the presence of vessels and/or the nervous plexus. In some embodiments, the lateral approach may be particularly pertinent when correcting spondylolisthesis in the lumbar region of the spine, although it will be understood that other regions of the spine are also contemplated.

Referring to FIGS. 3a and 3b, **correction of spondylolisthesis can be addressed from a lateral approach by, for example, providing a pair of bone screws 30, 32 for insertion into the vertebrae V_U , V_L , respectively.**

* * *

The bone screws 30, 32 may be linked to one another via a rod 34 ... By applying a rotating force to the rod 34 in the direction of arrow 36, the upper vertebra V_U is encouraged back into a desired position relative to the lower vertebra V_L . The rotating force can be applied, for example, by a rotatable wrench (not shown) that can be used by a surgeon. It is understood that the upper vertebra V_U may not reach entirely to a fully corrected position in relation to the lower vertebra V_L , but the displacement can at least be reduced.

* * *

Referring to FIG. 7, to accommodate insertion of the offset prosthetic joint 40 within a spondylosed intervertebral space, **the partially corrected upper and lower vertebrae V_U , V_L can be prepared to accept the prosthetic joint 40 (shown in section in FIG. 7a) therebetween. Specifically, elongate openings or slots**

80, 82 may be formed along the vertebral endplates of the upper and lower vertebrae V_U , V_L , respectively, at a predetermined width and to a predetermined depth.

* * *

Referring to FIG. 8, in one embodiment, **the upper and lower vertebrae V_U , V_L may be fully corrected, and thus, an alternative articulating prosthetic joint 90 may be used in correcting spondylolisthesis**. The articulating joint 90 may be substantially similar to the prosthetic joint 40 with the exception of the orientation of various elements of the articulating joint 90. For example, **to accommodate insertion into fully corrected upper and lower vertebrae V_U , V_L** , the articulating joint 90 may include a laterally-extending keel 92 that is substantially centered on an upper articulating component 94 of the articulating joint and a laterally-extending keel 96 that is substantially centered on a lower articulating component 98. ... In one embodiment, the upper and lower articulating components 94, 98 are substantially flush with one another **when disposed between fully corrected upper and lower vertebrae V_U , V_L** .

To accommodate insertion of the offset prosthetic joint 90, **the fully corrected upper and lower vertebrae V_U , V_L can be prepared to accept the prosthetic joint 90 therebetween**. Specifically, elongate openings or slots 104, 106 may be formed along the vertebral endplates of the upper and lower vertebrae V_U , V_L , respectively, at a predetermined width and to a predetermined depth. The slots 104, 106 can be substantially aligned with each other **to accommodate the fully corrected upper and lower vertebrae V_U , V_L** .

* * *

Referring to FIG. 9, in an alternative embodiment, **a slidable prosthetic joint 110 can be used to help with the lateral approach for treating spondylolisthesis**.

It is clear from this disclosure from the "Lateral Correction" portion of the application that the combination of limitations set forth in claims 14-16 and 31-40 are fully supported by the disclosure. In particular, it is more than apparent that the specification discloses (1) creating the intervertebral space S for receiving a prosthetic joint, (2) partially or fully correcting the

spondylosed relationship between the upper and lower vertebrae from a lateral approach using the rod and bone screws, and (3) laterally inserting the prosthetic joint into the intervertebral space'S after the partial or full correction of the spondylosed relationship. The Examiner's position otherwise is clearly contrary to the explicit disclosure of the present application. As the specification clearly enables the combination of limitations set forth in claims 14-16 and 31-40, Applicants request that the § 112 rejections of claims 14-16 and 31-40 be withdrawn.

C. Rejections under 35 U.S.C. §102

Claims 12, 13, 17, 21, 31-35, and 38 stand rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,108,395 to Laurain ("the Laurain patent"). The PTO provides in MPEP § 2131 that

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). ... "The identical invention must be shown in as complete detail as is contained in the ... claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). (emphasis added)

Therefore, to sustain the rejection of claims 12, 13, 17, 21, 31-35, and 38 the Laurain patent must disclose each and every element in as complete detail as recited in the claims.

First, as a preliminary matter, the present Office Action notes that "In response to applicant's argument that Laurain discloses a method for correcting kyphoses and not spondylolisthesis, a recitation of intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim." Office Action, p. 11. This statement is incorrect as a matter of law. All of Applicants' pending claims are **methods claims**, not apparatus or articles. As noted in MPEP § 2114, it is a requirement of **apparatus and article claims** that the claimed apparatus or article be structurally distinguished from the prior art. There is simply no such requirement for method claims such as those pending in the present case. Rather, the Examiner is required to consider each and every element in as complete detail as recited in the claims.

Accordingly, for this fundamental reason it is clear that the Examiner's basis for rejecting claims 12, 13, 17, 21, 31-35, and 38 based on Laurain is unfounded.

In that regard, the Laurain patent entirely fails to disclose correcting spondylolisthesis. There is no mention of spondylolisthesis anywhere in the Laurain patent. Rather, the Laurain patent is focused on "the correction of kyphoses caused by the destruction of one or two vertebral bodies." Thus, the Laurain patent necessarily fails to disclose each and every element in as complete detail as recited in independent claims 12 and 31, which are directed to methods of correcting spondylolisthesis.

Further, with respect to independent claims 12 and 31, the Laurain patent at least fails to disclose "applying a rotating force directly to the connecting member from a substantially lateral approach after engagement of the connecting member with the first and second insertion members to rotate the first and second vertebrae relative to one another to reduce the spondylosed relationship therebetween." First, the Laurain patent explicitly notes that "[t]he subject of the present invention is an implant for anterior dorsolumbar spinal osteosynthesis," "the object of the invention is therefore to provide an implant having the advantages of these two categories of prior devices without having their disadvantages so as to carry out an anterior reconstruction of the dorso-lumbar spine," and "[t]he implant 1 [is] intended to be fitted anteriorly onto the vertebral bodies." Col. 1, ll. 6-9, Col. 2, ll. 31-36, and Col. 4, ll. 13-14 (emphasis added).

Further still, the vertebrae in the Laurain patent are moved by distracting forceps, not by rotating the plate 6. Specifically, the Laurain patent states that "[t]he surgeon then fits the distracting forceps (FIG. 7), the tips 21a of which fit into the notches 23 against which they bear, so as to permit distraction and to correct the kyphosis." Col. 6, ll. 65-68. With respect to the plate 6 and clamps, the Laurain patent notes that "means for adjusting the angle of the plate 6 relative to the clamps 2 and for locking in rotation (complementary serrations 18 and 19) enable the implant to be fitted with a maximum amount of flexibility, and likewise adaptability to the anatomical conditions of the spinal segment in question." Col. 7, ll. 47-52. In other words, the clamps and plate are adjusted to the orientation of the vertebrae. The plate is simply not rotated

to adjust the orientation of the vertebrae, let alone correct spondylolisthesis from a lateral approach as required by claims 12 and 31.

For at least these reasons, the Laurain patent fails to disclose each of the recited elements of independent claims 12 and 31. Claims 13, 17, 21, 32-35, and 38 depend from and further limit claims 12 and 31. Thus, Applicants request that the §102 rejection of claims 12, 13, 17, 21, 31-35, and 38 be withdrawn.

D. Rejections under 35 U.S.C. §103

1. Laurain Patent

Claim 36 stands rejected under 35 U.S.C. §103(a) as being unpatentable over the Laurain patent. As shown above, however, the Laurain patent fails to disclose each of the elements of independent claim 31 from which claim 36 depends from and further limits. Accordingly, for at least the same reasons the Laurain patent fails to disclose or suggest all of the elements of claim 36. Thus, Applicants request that the §103 rejection of claim 36 over the Laurain patent be withdrawn.

2. Laurain, Jacobsen, and Conchy Patents

Claim 37 stands rejected under 35 U.S.C. §103(a) as being unpatentable over the Laurain patent in view of U.S. Patent No. 5,382,248 to Jacobson et al. (“the Jacobson patent”) and U.S. Patent No. 6,749,612 to Conchy et al. (“the Conchy patent”). As shown above, the Laurain patent fails to disclose each of the elements of independent claim 31, from which claim 37 depends from and further limits. The Jacobson and Conchy patents do not affect this deficiency. Accordingly, even when combined the Laurain, Jacobson, and Conchy patents fail to disclose all of the recited elements of claims 37. Thus, Applicants request that the §103 rejection of claim 37 over the Laurain, Jacobson, and Conchy patents be withdrawn.

3. Jackson, Conchy, and Kapp Patents

Claims 12, 13, 17, 20, 21, and 31 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,591,165 to Jackson (“the Jackson patent”) in view of the Conchy patent and U.S. Patent No. 4,554,914 to Kapp et al. (“the Kapp patent”).

The PTO provides in MPEP §2131 that

“The examiner bears the initial burden of factually supporting any prima facie conclusion of obviousness. If the examiner does not produce a prima facie case, the applicant is under no obligation to submit evidence of nonobviousness.”

The Examiner clearly cannot, using the Jackson, Conchy, and Kapp patents, establish a prima facie case of obviousness in connection to claims 12, 13, 17, 20, 21, and 31 for at least the following reasons.

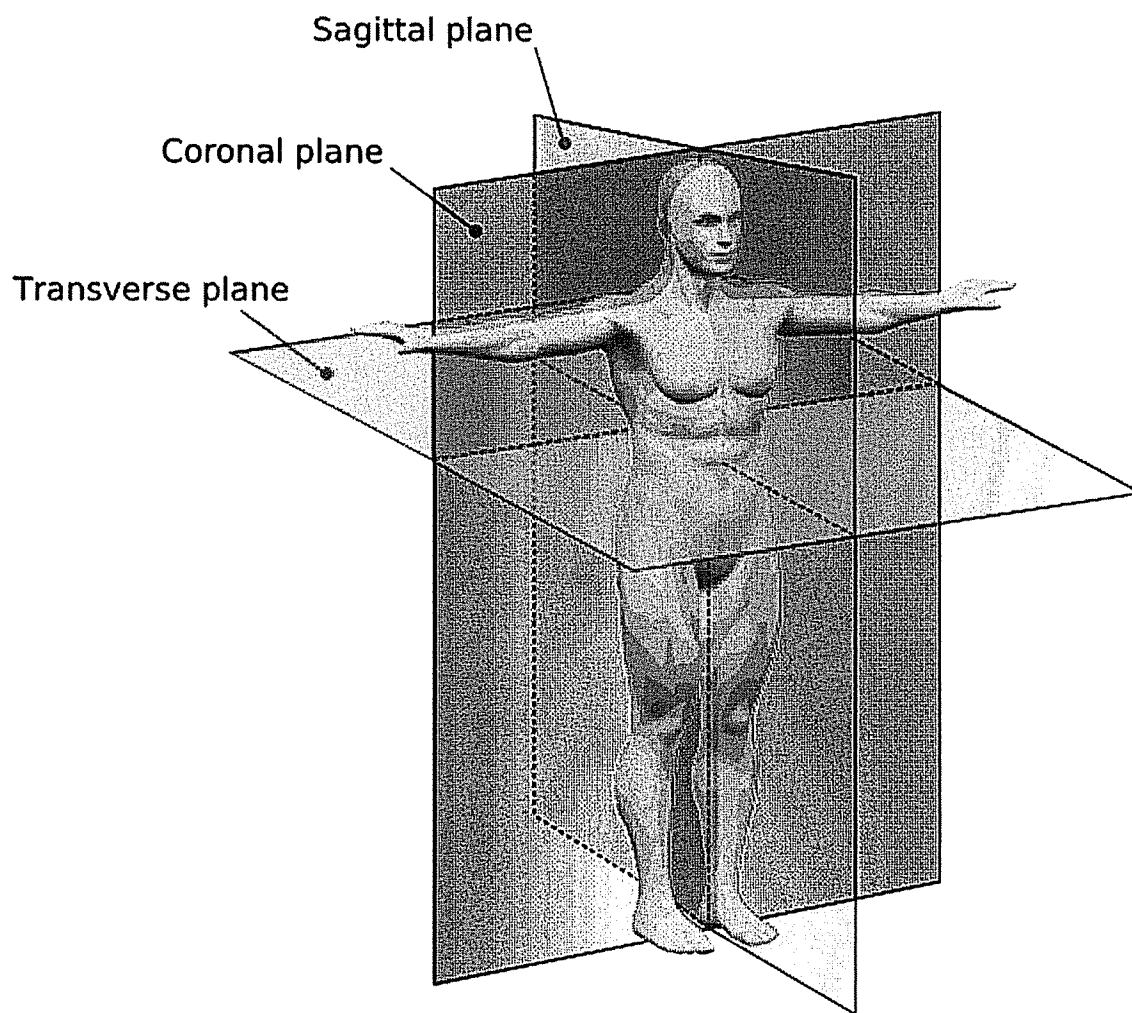
35 U.S.C. §103(a) provides, in part, that:

“A patent may not be obtained . . . if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time of the invention was made to a person having ordinary skill in the art . . .”
(emphasis added)

Thus, when evaluating a claim for determining obviousness, all limitations of the claim must be evaluated. However, even when combined the Jackson, Conchy, and Kapp patents fail to disclose all of the recited limitations of claims 12, 13, 17, 20, 21, and 31.

For example, with respect to independent claim 12, the Jackson patent fails to disclose “laterally inserting a first insertion member into a lateral sidewall of the first vertebra such that the first insertion member does not extend within the intervertebral space and does not engage a pedicle of the first vertebra; laterally inserting a second insertion member into a lateral sidewall of the second vertebra such that the second insertion member does not extend within the intervertebral space and does not engage a pedicle of the second vertebra,” as recited. Instead, as clearly shown in Figs. 3-5, 9A, 9B, 9C, 11A, 11B, and 17A-20B of the Jackson patent, the bone screws of the Jackson patent are introduced through the pedicles of the vertebrae from a lateral approach. The Examiner asserts that the approach in Jackson should be considered lateral because it is in the sagittal plane. Office Action, p. 8. However, the fact that the approach is in the sagittal plane simply confirms the fact that Jackson discloses a posterior approach. As shown in the diagram reproduced below, the sagittal plane runs vertically through the body. Thus, an approach that is “in the sagittal plane” necessarily travels only in the anterior/posterior

directions. Therefore, the Examiner's assertion that such an approach is a lateral approach cannot be supported.



As the Jackson patent entirely fails to disclose laterally inserting first and second insertion members into the lateral sidewalls of the first and second vertebrae, the Jackson patent necessarily fails to disclose “applying a rotating force directly to the connecting member from a substantially lateral approach after engagement of the connecting member with the first and second insertion members to rotate the first and second vertebrae relative to one another to reduce the spondylosed relationship therebetween.” In that regard, Applicants again disagree that the disclosure of rotating of a rod in the sagittal plane is rotation from a substantially lateral approach as required by claim 12. The Jackson patent notes that “This force application is

possible with screws advanced through the pedicles from a posterior approach.” Further, as noted above, Figs. 3-5, 9A, 9B, 9C, 11A, 11B, and 17A-20B of the Jackson patent illustrate the bone screws being introduced into the pedicles of the vertebrae from a posterior approach. There is simply no mention or disclosure of utilizing a lateral approach in the Jackson patent. Thus, the Jackson patent necessarily fails to disclose the above-recited limitations of claim 12.

For at least these reasons, even when combined the Jackson, Conchy, and Kapp patents fail to disclose or suggest all of the recited limitations of independent claim 12. Claims 13, 17, 20, and 21 depend from and further limit claim 12. Thus, a *prima facie* case of obviousness has not been established with respect to claims 12, 13, 17, 20, and 21. Therefore, Applicants request that the § 103 rejection of claims 12, 13, 17, 20, and 21 over the Jackson, Conchy, and Kapp patents be withdrawn.

Independent claim 31 recites limitations similar to those discussed above with respect to claim 12. For example, claim 31 requires “laterally inserting a first insertion member into a sidewall of the first vertebra such that the first insertion member does not extend within the intervertebral space and is spaced from a pedicle of the first vertebra; laterally inserting a second insertion member into a sidewall of the second vertebra such that the second insertion member does not extend within the intervertebral space and is spaced from a pedicle of the second vertebra; positioning an elongated member adjacent to and between the first and second insertion members; engaging the elongated member with the first and second insertion members; [and] applying a rotating force to the elongated member from a lateral approach to rotate the first and second vertebrae relative to one another to reduce the spondylosed relationship therebetween.” As discussed above, even when combined the Jackson, Conchy, and Kapp patents fail to disclose or suggest such limitations. Thus, a *prima facie* case of obviousness has not been established with respect to claim 31. Therefore, Applicants request that the § 103 rejection of claim 31 over the Jackson, Conchy, and Kapp patents also be withdrawn.

4. Jackson, Conchy, Kapp, and Marnay Patents

Claims 14-16, 39, and 40 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over the Jackson, Conchy, and Kapp patents in further view of the Marnay patent. As discussed

above, even when combined the Jackson, Conchy, and Kapp patents fail to disclose all of the recited elements of independent claims 12 and 31 from which claims 14-16, 39, and 40 depend and further limit. The Marnay patent does not affect this deficiency. Accordingly, for at least the same reasons the Jackson, Conchy, Kapp, and Marnay patents fail to disclose all of the limitations of claims 14-16, 39, and 40. Therefore, Applicants request that the §103 rejection of claims 14-16, 39, and 40 over the Jackson, Conchy, Kapp, and Marnay patents be withdrawn.

5. Jackson, Conchy, Kapp, and Wagner Patents

Claims 18 and 19 stand rejected under 35 U.S.C. §103(a) as being unpatentable over the Jackson, Conchy, and Kapp patents as applied to claim 17 in view of U.S. Patent No. 6,030,389 to Wagner et al. (“the Wagner patent”). As shown above, however, even when combined the Jackson, Conchy, and Kapp patents fail to disclose all of the elements of independent claim 12, from which claims 18 and 19 depend from and further limit. The Wagner patent does not affect this deficiency. Accordingly, even when combined the Jackson, Conchy, Kapp, and Wagner patents fail to disclose all of the recited elements of claims 18 and 19. Thus, Applicants request that the §103 rejection of claims 18 and 19 over the Jackson, Conchy, Kapp, and Wagner patents be withdrawn.

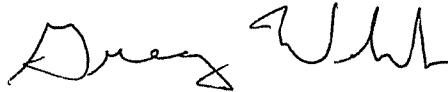
IV. Conclusion

It is believed that all matters set forth in the Office Action have been addressed and that all pending claims are in condition for allowance. Accordingly, Applicants request an indication of allowance of the pending claims.

The Office Action contains characterizations of the claims and the related art to which Applicants do not necessarily agree. Unless expressly noted otherwise, Applicants decline to subscribe to any statement or characterization in this or any other Office Action.

If an interview would expedite prosecution in any way, the Examiner is invited to contact the Applicants' undersigned representative.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Gregory P. Webb', with a stylized flourish at the end.

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